Lawrence A. Trissel, F.A.S.H.P.
2920 Carnegie Street
Houston, Texas 77005 1155 '99 JUN -8 A9:54

May 28, 1999

Dockets Management Branch
Food and Drug Administration (HFA-305), Room 1061
5630 Fishers Lane
Rockville, MD 20851

RE: Docket #98N-1265
Federal/State Memorandum of Understanding on
Interstate Distribution of Compounded Drug Products

Dear Sirs:

I would like to take advantage of the extension of the comment period on the draft Memorandum of Understanding between the Food and Drug Administration and participating State Boards of Pharmacy. I have a concern about the potential adverse impact on patients of one of its concepts.

The draft Memorandum of Understanding citing the Food and Drug Administration Modernization Act of 1997 proposes establishing limits for the percentage of prescriptions a pharmacy may compound and distribute interstate. A maximum of 20% of total prescriptions dispensed may be compounded and no more than 5% can be any one product or the pharmacy will be considered as distributing inordinate amounts of compounded drugs.

While I understand that the FDA is seeking to define "inordinate" for the purposes of this MOU, this limitation as currently defined works to the detriment of product quality and adequate patient care. I believe we should be encouraging the specialization of pharmacists and pharmacies that engage in compounding the many types of drugs necessary to patient care. The limitations as they are currently written place unwarranted barriers in the way of needed specialization.

Cardioplegia solutions will serve as a good example of products that benefit from encouraging specialization although many others, ranging from the simple and to the complex, are in similar situations. Cardioplegia solutions are complex multi-component sterile solutions that are essential for performing many cardiac surgical procedures. Modern cardiac surgical care could not be conducted without them. But they are only available as extemporaneously compounded sterile solutions. It would be far, far better for patients, care givers, regulators, and other interested parties to have these highly complex sterile products prepared in specialized high quality compounding pharmacy facilities by specially trained and very experienced compounding pharmacists whose practice involves mostly sterile product compounding. This is true even if the solutions must come from out of state. It would be much more risky for the pharmacist who rarely (or never) compounds a product having the demanding requirements of cardioplegia solutions and must use a marginally equipped compounding facility to compound the solutions.

98N-1265

EXT 10

Unfortunately, specialized highly trained and well experienced pharmacists working in specialty compounding pharmacies that do nothing but sterile product compounding would be precluded from providing the solutions out of state since these compounded products may constitute up to 100% of their prescriptions. All the while, the inexperienced pharmacist working in a marginal facility would be allowed to make the cardioplegia solution since compounded sterile solutions constitute such a small part of the overall operation.

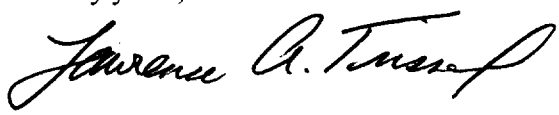
Simply put, that situation does not make sense. The industrialized world outside the U.S. has recognized for decades the need for specialized compounding pharmacies and have made suitable provisions for their operation within their legal and regulatory frameworks. Examples include The Netherlands, The United Kingdom, Canada, Australia, and more recently, even Mexico. These specialized compounding pharmacies may include both hospital-based and commercial (or retail) pharmacy-based operations. Because of their nature such specialized compounding pharmacies are unlikely to be on every street corner; indeed, I expect them to be relatively few in number. Rather, I see them developing as regional specialty compounding pharmacies that serve a population and area regardless of state boundaries.

As an interesting example of one such operation, Baxter Healthcare operates a specialized sterile product compounding pharmacy in Sydney, Australia that distributes products throughout the entire continent! I believe such high quality specialized compounding pharmacies could work here in the U.S. as well, bringing the quality advantages to patients that can accrue. Delivery even to relatively distant locales is simply a logistical issue that can be readily handled, especially in the U.S.

It would be inappropriate, to say the least, to limit or preclude the quality advantages that specialization can bring because of an arbitrary percentage limit on the number of prescriptions that can be compounded and be delivered across state lines. It would be doing a substantial disservice to both patients and caregivers.

I would encourage the Agency in its efforts to establish a suitable Memorandum of Understanding to recognize the great value in terms of patient safety and product quality that professional specialization of compounding pharmacies and pharmacists can bring to patient care. I believe the Memorandum of Understanding should not be worded in a way that precludes such specialized operations whose practices cross state boundaries as the MOU does now. Indeed, I would hope it could be worded in a way that would encourage pharmacies to bring the quality benefits of specialized training, procedures, and facilities to the performance of compounding that is essential to adequate patient care.

Sincerely yours,



Lawrence A. Trissel

Lawrence A. Trissel
2920 Carnegie Street
Houston, Texas 77005-3911

HOUSTON TX
PM
JUN
1999

Dockets Management Branch
Food and Drug Administration (HFA-305), Room 1061
5630 Fishers Lane
Rockville, MD 20851

20857/0003